REMARKS

Reconsideration is respectfully requested.

Claims 1, 3, 10, 12, and 15 are pending. Claim 1 has been amended for clarification. No new matter has been added.

Claims 1, 3,[1] 10, 12, and 15 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite with respect to the term "betaine." Applicants respectfully disagree and request reconsideration.

As amended previously, the claims recite administering "solid ciprofloxacin betaine or enrofloxacin betaine or a solid slightly soluble salt of ciprofloxacin betaine or enrofloxacin betaine." The claims do not recite a "betaine" form of any particular compound. Applicants take no position as to the art-accepted meaning of the term "betaine" in isolation because they submit that it is not relevant to the issue of definiteness. Instead, the relevant term to be construed is "ciprofloxacin betaine."

Whatever the art-accepted meaning of "betaine" in isolation may be, the meaning of "ciprofloxacin betaine" is well-known in the art and the person of ordinary skill in the art would immediately understand what is claimed. In fact, the Examiner has cited Kanikanti et al. (US 2004/0024018) as teaching in paragraphs [0039]-[0047] that ciprofloxacin betaine is known. *See* September 1, 2010 Office Action at page 5, point 10. In the reference, ciprofloxacin betaine is mentioned without the need for further elaboration to assist the skilled artisan in understanding what is meant. *See, e.g.*, col. 3, lines 1-7 of the corresponding issued U.S. Patent No. 7,709,022; and claim 2, which recites ciprofloxacin betaine.

In addition to Kanikanti and the references previously cited by the Applicants, the following examples also demonstrate that "ciprofloxacin betaine" has achieved the status of being well-known in the art:

[1] Although the Office Action states that "Claims 1, 2, 10, 12, and 15 are rejected …", it is understood that claim 3 was intended to be rejected for indefiniteness. Claim 2 was previously canceled, and claim 3 was not the subject of any rejection but is listed as rejected in the Office Action Summary.

U.S. Patent No. 6,605,069, col. 8, lines 52-53:

> Release profiles of polymer samples comprising active compounds. In each case the concentration [mg/1] of the active compound released from the polymer sample is stated.
>
> Example 1: Control sample of Hytrel® containing no active compound, Example 2*c:* 1.0 wt. % ciprofloxacin-betaine in Hytrel®, Example 2*d:* 1.0 wt. % doxycycline HCl in Hytrel®, Example 2*e:* 1.0 wt. % clindamycin HCl in Hytrel®, Example 2*f:* 1.0 wt. % lincomycin HCl in Hytrel®, Example 2*g:* 1.0 wt. % fusidic acid in Hytrel®.

U.S. Patent No. 6,495,613, col. 5, line 66:

> PREPARATION EXAMPLE 2
>
> Preparation of an Antibiotics-containing Polyurethane (Solvent Casting)
>
> "Walopur" polyurethane (Wolff, Walsrode) is extracted for 24 hours in a water/ethanol mixture (1:1) at 82° C. under reflux and subsequently dissolved in dimethylformamide (102° C., reflux). Ciprofloxacin-betaine is dissolved in this solution with a concentration of 750 ppm and the solvent is

U.S. Patent No. 6,723,333, col. 9, line 12:

> stirring at room temperature, to a solution of 71.6 parts by wt. of isophorone diamine in 2456 parts by wt. of a mixture of toluene and isopropanol (70/30). Then 11.74 g of ciprofloxacin-betaine (1.0 wt. % with respect to the polymer material) were stirred into the mixture. A colourless, transparent and homogeneous solution was obtained. After

Harder et al., Br. J. Clin. Pharmac. (1990), 30, 35-39 at 36:

> **Methods**
>
> *Study design*
>
> The pharmacokinetics of a single dose of ciprofloxacin (180 mg ciprofloxacin-betaine in 0.9 ml of a liquid preparation) were investigated in four healthy male volunteers (age 23–30 years) after releasing the substance in different parts of the gastrointestinal tract. All ciprofloxacin prepara-

(available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1368272/pdf/brjclinpharm00069-0040.pdf)

Olivera et al., J. Pharm. Sci. (2010) e-pub in advance of print, at 6:

Absorption and Permeability

No human jejunal perfusion studies were identified. The absorption of ciprofloxacin from different regions of the human GI tract was investigated in four healthy males using a special drug-releasing device (hf-capsule) by measuring the AUC after release of 180 mg ciprofloxacin–betaine in stomach, jejunum, ileum, and ascending colon. Significant differences in AUC were observed in the control study (oral

Moreover, "'the authors of dictionaries or treatises may simplify ideas to communicate them most effectively to the public and may thus choose a meaning that is not pertinent to the understanding of particular claim language. The resulting definitions therefore do not necessarily reflect the inventor's goal of distinctly setting forth his invention as a person of ordinary skill in that particular art would understand it.'" *Ultimax v. CTS Cement Manufacturing*, No. 08-1218, (Fed. Cir. Dec. 3, 2009) (quoting *Phlilips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

In *Ultimax*, the Federal Circuit agreed with the appellant that the district court "erroneously used the stand-alone definition of 'anhydride,' without context" and concluded that "the court erroneously relied on expert testimony and a single dictionary definition to the exclusion of other dictionary definitions and, most importantly, the context in which the term was used within the claim and the specification."

Here, as in *Ultimax*, it is incorrect to focus on the stand-alone definition of the term "betaine" when the meaning of "ciprofloxacin betaine" is clear to the skilled artisan. Accordingly, it is respectfully submitted that the claims are definite and the present rejection should be withdrawn.

Claims 1 and 15 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Pikiewicz et al. Claims 1 and 15 have also been rejected under 35 U.S.C. § 103 as being obvious

over Mayer et al. in view of Li et al.; Pikiewicz et al. in view of Kanikanti et al.; and Mayer et al. in view of Li et al. and Kanikanti et al.

Applicants reiterate that none of the primary references disclose ciprofloxacin betaine or enrofloxacin betaine, and the secondary references provide no motivation or rationale to use ciprofloxacin betaine or enrofloxacin betaine in a powder form or powder-containing suspension to treat bacterial diseases of the lungs. The Examiner appears to assert that the general teaching of ciprofloxacin in the cited references anticipates and contributes to the obviousness of the specific usage of ciprofloxacin betaine. Applicants disagree and request reconsideration and withdrawal of the rejection.

CONCLUSION

It is believed that the present application is in condition for allowance. If a telephone conference with Applicant's representative would be helpful in expediting prosecution of the application, Applicant invites the Examiner to contact the undersigned at the telephone number indicated below.

Dated: December 1, 2010

Respectfully submitted,
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